UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: GADOLINIUM BASED CONTRAST AGENTS PRODUCTS LIABILITY LITIGATION	Case No. 1:08 GD 50000 MDL No. 1909 JUDGE DONALD C. NUGENT
PAUL DECKER and KAREN DECKER, Plaintiffs, v. GE HEALTHCARE INC., *et al.*, Defendants.	Case No. 1:12-GD-50004

MEMORANDUM IN SUPPORT OF GEHC'S MOTION FOR A NEW TRIAL, TO ALTER OR AMEND THE JUDGMENT, AND FOR REMITTITUR

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MEMORANDUM IN SUPPORT OF GEHC'S MOTION FOR A NEW TRIAL, TO ALTER OR AMEND THE JUDGMENT, AND FOR REMITTITUR

On February 2, 2012, Plaintiffs Paul and Karen Decker filed this action alleging personal injuries and asserting claims under the Ohio Products Liability Act ("OPLA").[1] Plaintiffs alleged that Mr. Decker developed nephrogenic systemic fibrosis ("NSF")—a rare and potentially disabling skin disorder—as a result of his exposure to Omniscan. Omniscan is a gadolinium-based contrast agent ("GBCA") found to be "safe and effective" by the United States Food and Drug Administration ("FDA") even today and distributed, sold, and marketed in the United States by Defendant GE Healthcare Inc. Mr. Decker's physicians administered Omniscan to him during a September 2, 2005 magnetic resonance ("MR") procedure to diagnose a potentially life-threatening medical condition. As of September 2, 2005, Omniscan was one of five GBCAs on the market. Mr. Decker's administration of Omniscan occurred before any association between NSF and GBCAs was first identified in January 2006. At trial, Plaintiffs pursued claims under the OPLA for (1) design defect, (2) inadequate warning, and (3) nonconformance with representations. GEHC denied liability and asserted various defenses, including the statute of limitations on which the jury was instructed.

Following a twelve-day trial and nearly two full days of deliberations, the jury returned a verdict in favor of GEHC on Plaintiffs' claims for design defect and nonconformance to representations and found in favor of Plaintiffs on their inadequate warning claim. The jury awarded $1 million in damages for economic loss to Mr. Decker, $3.5 million in damages for

[1] Because the trial judge recused himself (*see* Order of Recusal, Apr. 8, 2013 (*Decker* ECF No. 225), at 1 & Order of Recusal and Reassignment, Apr. 22, 2013 (*Decker* ECF No. 269)), and because recusal is from an entire proceeding, not simply an individual motion or issue (*see infra* at 35–45), GEHC provides more background than it ordinarily would for the benefit of a judge less familiar with the facts of this case to aid in the process of certifying familiarity with the record pursuant to Rule 63. For this reason, GEHC also attaches as Exhibit 1 a brief list of the witnesses who testified at trial. Because the Order of Recusal and Reassignment was not entered until three days before the deadline for filing this motion, GEHC reserves the right to develop its arguments regarding the issues triggered by the recusal further.

non-economic loss to Mr. Decker, and $500,000 in damages for loss of consortium to Mrs. Decker, for a total verdict of $5 million.

SUMMARY OF THE ARGUMENT

Defendants GE Healthcare Inc. and GE Healthcare AS (collectively, "GEHC") respectfully request that the Court order a new trial on Plaintiffs' inadequate warning claim, alter or amend the judgment, or alternatively grant remittitur of the jury's award of economic damages. The following are among the grounds for this motion:

First, Plaintiffs' inadequate warning claim suffers from a fatal failure of proof. Plaintiffs failed to present evidence that any inadequate warning proximately caused Mr. Decker's injuries. Because Omniscan is a prescription drug, Ohio's learned intermediary doctrine directs that warnings be provided to the prescribing doctors, not Mr. Decker himself. Mr. Decker's physicians testified that specific or additional warnings from GEHC would not have changed their decisions about how to treat Mr. Decker in 2005. For that to happen, the information they needed was the association between NSF and Omniscan, which did not happen until 2006—months *after* Mr. Decker received an administration of Omniscan on September 2, 2005. Even Plaintiffs did not claim at trial that GEHC should have or could have warned of the risk of NSF in 2005. Moreover, the evidence at trial demonstrated that the material information about which Plaintiffs argued GEHC should have warned already appeared on the product's labeling by September 2, 2005 when Mr. Decker received an administration of Omniscan. Plaintiffs failed to carry their burden of presenting evidence of a specific or additional warning that would have prevented Mr. Decker's injury. (*See infra* at 16–27.)

Further, Plaintiffs' inadequate warning claim turned on four reports of adverse reactions or events following administration of Omniscan in other patients between 2002 and 2005. The

Court recognized the need to explain this sort of unfamiliar evidence to the jury as well as the impropriety of using these reports to show that Omniscan caused any symptom or injury. Nonetheless, reversing its prior ruling, the Court declined to give a limiting instruction to place this evidence, which consumed an inordinate amount of Plaintiffs' time at trial, into its proper legal and evidentiary context. (*See infra* at 27–32.) Finally, improperly admitted evidence regarding the actions of a foreign regulatory agency unfairly prejudiced GEHC and tainted the verdict on Plaintiffs' inadequate warning claim. Specifically, the Court should have excluded evidence regarding the decision of a Danish governmental agency that administers a no-fault patient compensation fund to compensate one of the patients who reported adverse reactions following administration of Omniscan. That evidence, repeatedly emphasized by Plaintiffs at trial and argued in closing, underscores Plaintiffs' failure of proof and invited the jury to decide liability on improper grounds. (*See infra* at 32–35.)

Second, the trial judge's recusal requires a new trial to avoid the appearance of partiality and to maintain public confidence in the administration of justice. Before trial, the trial judge was heavily involved in efforts to settle this case. After trial, Plaintiffs' moved for prejudgment interest, which prompted the trial judge to raise the prospect of recusal on his own during a hearing. Counsel for GEHC pointed out that, under both state and federal law, recusal due to involvement in settlement efforts ordinarily is not required. Nonetheless, the trial judge recused himself from deciding Plaintiffs' motion for prejudgment interest because he did not believe he could be fair and impartial in deciding whether either party negotiated in good faith. Against this backdrop, the trial judge's recusal reflects feelings so significantly affected by involvement in pre-trial settlement discussions or so deeply held that he did not believe he could be fair and

impartial in passing judgment on the conduct of the parties. Nonetheless, the trial judge presided over the trial during which he made numerous discretionary and legal rulings.

Whatever it is about the trial judge's involvement in settlement efforts before trial that led to his recusal post-trial counsels that the trial judge should not have presided at trial. Even in the absence of evidence of actual bias or partiality, the Supreme Court has held that recusal under such circumstances requires a new trial to maintain public confidence in the judiciary and avoid the risk of unfairness to the parties. (*See infra* at 35–45.)

Finally, GEHC also requests remittitur or a new trial based on the Court's error in refusing to admit evidence of showing actual economic loss from past medical bills and the Plaintiffs' failure to produce evidence of compensable mental distress. These errors allowed the jury to make a speculative award of economic loss that permeated the entire damages award.

For all these reasons, as more fully explained below, the Court should order a new trial or alter or amend the judgment.

STATEMENT OF FACTS

A. Plaintiff Paul Decker

Even before his administration of Omniscan, Plaintiff Paul Decker has a long and complicated medical history unrelated to NSF. (Trial Tr., Mar. 8, 2013, at 980:17–82:6, 1011:1–20:24 & 1029:14–36:6 (testimony of P. Decker).) His severe and debilitating conditions include end-stage renal (kidney) disease, esophageal cancer, endocarditis (an infection of the heart), an automatic implantable cardioverter defibrillator (a medical device implanted in the body to treat irregular, and potentially life-threatening, heart rhythms), heart disease requiring coronary artery bypass graft surgery, congestive heart failure with a reduced ejection fraction resulting in an increased risk of sudden cardiac death, aortic valve replacement requiring lifetime administration

of blood thinners, hypertension, obstructive lung disease, arthritis and degenerative joint disease, peripheral vascular disease, hyperparathyroidism, and a heavy smoking history that includes, as of 2005, smoking two packs of cigarettes per day for more than thirty years. (*Id*; Trial Tr., Mar. 13, 2013, at 1882:22–1883:7 & 1889:1–8 (testimony of Dr. Fine).) It was undisputed at trial that these serious co-morbidities greatly increase Mr. Decker's risk of premature death. (Trial Tr., Mar. 13, 2013, at 1886:12–1889:15 (testimony of Dr. Fine); Trial Tr., Mar. 15, 2013, at 2300:2–2302:15 (testimony of Dr. Weisbord).) He applied for total disability benefits in 2005—four years before onset of any NSF symptoms—as a result of his end-stage renal disease and continues to receive those benefits today. (Trial Tr., Mar. 8, 2013, at 981:18–25 (testimony of P. Decker).)

In August 2005, Mr. Decker developed a heart infection, which caused his kidneys to fail—a clinical presentation his physicians described as an "unusual situation." (Trial Tr., Mar. 11, 2013, at 1109:21–23 & 1110:16–20 (testimony of Dr. Shaffer).) To evaluate the severity of his heart infection and his overall cardiac condition in advance of heart surgery, Mr. Decker's thoracic surgeons consulted with Dr. Phillip Shaffer, a radiologist at Riverside Radiology Associates in Columbus, Ohio, who was Mr. Decker's treating radiologist at all relevant times. Dr. Shaffer ordered an MR procedure on September 2, 2005, using a standard dose of Omniscan. (*Id*. at 1110:23–1111:20.) Dr. Shaffer testified that this administration of Omniscan was medically appropriate and consistent with the standard of care at the time. (*Id*. at 1111:21–1113:6.) Mr. Decker began experiencing symptoms of NSF in 2009—four years after his Omniscan administration. (Trial Tr., Mar. 8, 2013, at 1021:5–1028:10 (testimony of P. Decker); Trial Tr., Mar. 13, 2013, at 1932:3–7 (testimony of K. Decker); Trial Tr., Mar. 15, 2013, at 2317:10–15 (testimony of Dr. Weisbord).)

B. Background on MR Procedures and GBCAs

GBCAs, including Omniscan, were developed in the late 1980s and early 1990s to enhance the images generated by magnetic resonance ("MR") imaging machines. MR procedures offer a non-invasive means of visualizing soft tissues within the body and help doctors diagnose and treat potentially life-threatening conditions without the use of ionizing radiation required for x-rays and CT scans. GBCAs were considered a medical breakthrough in diagnostic imaging because they substantially improved the quality of images generated by MR procedures. By administering GBCAs like Omniscan, physicians are able to identify diseases that may otherwise be difficult to detect and distinguish between certain types of tumors that may appear identical without contrast. (*See generally* Trial Tr., Mar. 14, 2013, at 2167–75 (testimony of Dr. Cohan).)

At the time Mr. Decker received an administration of Omniscan in 2005, not only were GBCAs including Omniscan considered highly effective at producing superior images for diagnostic purposes, but clinical experience involving millions of GBCA administrations also proved they were extremely safe. (*See* Trial Tr., Mar. 14, 2013, at 2177:4–2184:20, 2189:3–2191:4 & 2212:6–2113:8 (testimony of Dr. Cohan); Trial Tr., Mar. 19, 2013, at 2744:8–2745:11 (testimony of Dr. Feigal).) Indeed, before the association of NSF with GBCAs in 2006, GBCAs were widely thought to be "among the safest drugs ever marketed." (Trial Tr., Mar. 6, 2013, at 344:15–18 (testimony of Dr. Raymond).) Early experience with GBCAs revealed that they did not carry the serious risk of contrast-induced nephropathy (renal failure caused by a contrast agent) and allergic reaction that existed with the administration of iodinated contrast agents used during CT scans. (Trial Tr., Mar. 14, 2013, at 2169:2–2171:6 (testimony of Dr. Cohan).) By 1999 and through September 2, 2005, scientific studies established Omniscan as one of the safest GBCAs on the market. (*Id.* at 2178:9–2181:19 (testimony of Dr. Cohan).)

C. Development and FDA Approval of Omniscan

GEHC and its predecessors conducted an extensive battery of chemical, physicochemical, animal, and human studies before the FDA approved Omniscan for sale in the United States. Prior to approval, GEHC provided over 100,000 pages of scientific data on Omniscan to the FDA. This included more than 40 animal studies, 10 *in vitro* studies, and data from clinical studies with nearly 500 patients. The FDA approved Omniscan as safe and effective in January 1993. (Trial Tr., Mar. 19, 2013, at 2735–36, 2740–41, 2757–58 & 2761–63 (testimony of Dr. Feigal); DX5048 (Decker ECF No. 246-7 (PAGEID# 19361).[2])

The FDA also approved the package insert, or labeling, for Omniscan before it was first marketed in 1993. (Trial Tr., Mar. 12, 2013, at 1585–86 (testimony of C. Blume, Ph.D.); DX5067 (Decker ECF No. 246-8 (PAGEID# 19418).)) The evidence at trial confirmed that FDA approval of the labeling was required before GEHC's predecessors could market Omniscan. (Trial Tr., Mar. 12, 2013, at 1585–86 (testimony of C. Blume, Ph.D.); Trial Tr., Mar. 19, 2013, at 2761:2–2763:25 (testimony of Dr. Feigal).) Pursuant to FDA regulations, the package insert includes sections containing warnings and precautions for the product's use. (*Id.*) Omniscan's FDA-approved package insert always has warned physicians to exercise caution when administering Omniscan to patients, such as Mr. Decker, with renal impairment because Omniscan is cleared from the body through the kidneys. (*See* DX 5205 (*Decker* ECF No. 246-10) ("Since OMNISCAN is cleared from the body by glomerular filtration, caution should be exercised in patients with impaired renal function.") & ("[C]aution should be exercised in patients with renal insufficiency with or without hepatic impairment.").) Because Omniscan is a drug administered to patients only by prescription, Ohio law through the learned intermediary doctrine requires that GEHC

warn prescribing doctors, not Mr. Decker himself. (Trial Tr., Mar. 20, 2013, at 2980:10–17 (final jury charge).)

By September 2, 2005, when Mr. Decker had his MR procedure and received an administration of Omniscan, Omniscan's labeling contained a precaution warning of "serious, life threatening, fatal, anaphylactoid" and other adverse reactions, including idiosyncratic reactions:

> The possibility of a reaction, including serious, life threatening, fatal, anaphylactoid or cardiovascular reactions or other idiosyncratic reactions should always be considered . . . .

(DX5205 (*Decker* ECF No. 246-10).) The labeling also warned of adverse reactions, including anaphylactoid reactions with cutaneous (*i.e.*, skin) effects, pain, arthralgia (*i.e.*, joint pain), myalgia (*i.e.*, muscle pain), and skin disorders:

> **ADVERSE REACTIONS**
>
> The most frequent adverse event observed during OMNISCAN clinical trials were nausea, headache, and dizziness that occurred in 3% or less of the patients; other adverse events that occurred in 1% or less of the patients are listed below. *This includes all reported adverse events regardless of attribution*. The majority of these adverse events were of mild to moderate intensity. Dose and adverse event relationships are not fully clarified.
>
> **The following adverse events occurred in 1% or less of the patients:**
>
> * * *
>
> ***Body as a Whole—General Disorders:*** Anaphylactoid reactions (characterized by cardiovascular, respiratory, and cutaneous symptoms), asthenia, chest pain, fatigue, fever, hot flushes, malaise, pain, rigors, syncope.
>
> * * *

[2] Items appearing on the MDL docket, Case No. 1:08-gd-50000, are identified by "MDL ECF" and the specific docket entry number. Items appearing on the *Decker* docket are identified by "*Decker* ECF" and the specific docket entry number.

> ***Musculoskeltal System Disorders:*** Arthralgia, myalgia.
>
> ***Psychiatric Disorders:*** Anorexia, anxiety, personality disorder, somnolence.
>
> ***Respiratory System Disorders:*** Rhinitis, dyspnea.
>
> ***Skin and Appendage Disorders:*** Pruritis, rash, erythematous rash, skin discoloration, sweating increased, urticaria.
>
> * * *
>
> ***Urinary System Disorders***: Acute reversible renal failure

(*Id.*) These warnings, including the same precautionary language regarding use of Omniscan in patients with severe renal impairment FDA approved in the original labeling, were included on the labeling of every package insert for Omniscan, including the one in force on September 2, 2005. (*Id*.)

During the years of Omniscan's research and development (1988–93), and for the next *twelve years* following Omniscan's release onto the U.S. market (1993 to January 2006), there was no evidence of a potential association between NSF and any GBCA, including Omniscan. (Trial Tr., Mar. 19, 2013, at 2783–85 (testimony of Dr. Feigal); Trial Tr., Mar. 13, 2013, at 1895–96 (testimony of Dr. Fine); Trial Tr., Mar. 11, 2013, at 1341:7–1342:22 (testimony of Dr. Semelka).) Moreover, Omniscan remains on the market today as a "safe and effective" FDA-approved diagnostic imaging agent. (Trial Tr., Mar. 14, 2013, at 2236:2–3 (testimony of Dr. Cohan); Trial Tr., Mar. 19, 2013, at 2735–36 (testimony of Dr. Feigal).)

D. Nephrogenic Systemic Fibrosis

NSF was not recognized as a disease until 2000—some seven years after FDA approved Omniscan—when Dr. Shawn Cowper, a dermatopathologist at Yale University, first described it in the medical literature. (Trial Tr., Mar. 12, 2013, at 1612:12–1613:21 (testimony of C. Blume,

Ph.D.); *see also* Trial Tr., Mar. 19, 2013, at 2790 (testimony of Dr. Feigal) (discussing S.E. Cowper, *et al.*, *Scleromyxoedema-Like Cutaneous Disease in Renal-Dialysis Patients*, 356 Lancet 1000 (2000)) (attached as Ex. 5).) NSF is an "extremely rare" disease that is difficult to diagnose because it "shares features with other more common skin conditions, cellulitis, even rare, but still more common, like scleroderma." (Trial Tr., Mar. 13, 2013, at 1954:25–1955:3 (testimony of Dr. Cairns).) The symptoms of NSF are highly variable in the length of time to onset of the disease following administration of a GBCA (ranging from days to years), the level of skin involvement, the areas of the body affected, the amount of pain patients experience, and the level of disability patients experience. (Trial Tr., Mar. 13, 2013, at 1848–58 & 1900 (testimony of Dr. Fine).) While NSF only occurs in those with advanced kidney disease, many of the skin conditions that are associated with kidney failure are also associated with NSF. (Trial Tr., Mar. 15, 2013, at 2334:3–15 (testimony of Dr. Weisbord).)

Between 2000 when NSF was identified as a new disease and 2006 when an association between NSF and GBCAs was first identified in patients with severely impaired kidney function, more than 175 investigators and researchers from many different disciplines published a total of 44 articles examining potential causes of NSF. (Trial Tr., Mar. 15, 2013, at 2339:21–2340:4 (testimony of Dr. Weisbord); Notice of Filing of Documents Considered by the Jury, Apr. 10, 2013 (*Decker* ECF No. 248), at 24 (PAGEID# 20649).) Not one of these articles mentioned GBCAs as having any causative role. (Trial Tr., Mar. 15, 2013, at 2339:16–21 (testimony of Dr. Weisbord).) The state of medical knowledge during this period is best summarized by Dr. Cowper, who identified the disease now known as NSF and continued to research it to try to determine its cause. (Trial Tr., Mar. 12, 2013, at 1615:12–1616:2 (testimony of C. Blume, Ph.D.).) In October 2005, just one month after Mr. Decker's Omniscan administration, Dr.

Cowper described the cause of NSF as a "baffling mystery." (*Id.* at 1615:12–1616:2.) At bottom, as of September 2, 2005 when Mr. Decker received his Omniscan administration, the medical community understood little about NSF and its causes, knowing only that NSF appeared in patients with severe kidney disease. (Trial Tr., Mar. 15, 2013, at 2338:24–2340:4 (testimony of Dr. Weisbord).)

E. Adverse Event Reports

Between 2002 and 2005, GEHC and its predecessors received four adverse event reports ("AERs") on which Plaintiffs premised their failure to warn claim. These four AERs followed a decade of use of millions of doses of Omniscan in patients around the world. (Trial Tr., Mar. 12, 2013, at 1587:2–10 (testimony of C. Blume, Ph.D.).) None of these four AERs carried a diagnosis of NSF as of September 2, 2005. (Trial Tr., Mar. 19, 2013, at 2789:21–2790:1 (testimony of Dr. Feigal).) These four AERs reported varied and generalized symptoms that included arthralgia, myalgia, pain, and severe allergic reactions, each of which was reported on Omniscan's labeling by September 2, 2005:

Patient 0042.[3] GEHC's predecessor received notice of this AER on April 15, 2002. (Trial Tr., Mar. 19, 2013, at 2657:13–15 (testimony of Dr. Flaten).) That report advised that a 48-year old man in Denmark experienced symptoms of myalgia, sequelae, and renal impairment following an administration of Omniscan in 2002. (Trial Tr., Mar. 8, 2013, at 833:20–834:11, 910:14–20 (testimony of Dr. Flaten); Trial Tr., Mar. 19, 2013, at 2662:13–17 (testimony of Dr. Flaten).) As of September 2, 2005, these symptoms were not diagnosed as NSF. (Trial Tr., Mar. 19, 2013, at 2789:21–90:1 (testimony of Dr. Feigal).)

[3] Due to patient privacy concerns, the AERs (with the exception of the second AER involving Patient 0081 whose identity became known) were not referred to by name.

Patient 0081. GEHC's predecessor received notice of this AER on March 10, 2003. (Trial Tr., Mar 19, 2013, at 2664:13–15 (testimony of Dr. Flaten).) In separate proceedings, this patient was identified as Birthe Madsen. (Trial Tr., Mar. 8, 2013, at 909:5–8 (testimony of Dr. Flaten).) That report advised that a 55-year old woman in Denmark experienced symptoms of myalgia, arthralgia, and subcutaneous nodules following an administration of Omniscan in 2002. (Trial Tr., Mar. 19, 2013, at 2665:25–2666:2 (testimony of Dr. Flaten); DX5618 (*Decker* ECF No. 246-23).) As of September 2, 2005, these symptoms were not diagnosed as NSF. (Trial Tr., Mar., 19, 2013, at 2793:19–22 (testimony of Dr. Feigal).)

Patient 0355. GEHC's predecessor received notice of this AER on December 8, 2004. (Trial Tr., Mar. 19, 2013, at 2696:15–18 (testimony of Dr. Flaten).) That report advised that a 61-year old woman in Texas experienced symptoms of induration (*i.e.*, sclerosis or hardening), lymphedema (*i.e.*, fluid retention and tissue swelling), and vasculitis (*i.e.*, an inflammatory disorder that destroys blood vessels) following an administration of Omniscan in 2004. (Trial Tr. Mar. 19, 2013, 2671:10–13 (testimony of Dr. Flaten); Trial Tr., Mar. 19, 2013, at 2794–2795 (testimony of Dr. Feigal).) As of September 2, 2005, these symptoms were not diagnosed as NSF. (Trial Tr., Mar. 19, 2013, at 2795:13–18 (testimony of Dr. Feigal).)

Patient 0168. GEHC's predecessor received notice of this AER on July 18, 2005. (Trial Tr., Mar. 19, 2013, at 2673:3–6 (testimony of Dr. Feigal).) That report advised that a 47-year old man in Germany experienced symptoms of peripheral edema (*i.e.*, swelling), pain of the skin, muscle pain, and myalgia following an administration of Omniscan in 2005. (Trial Tr., Mar. 19, 2013, at 26737–11 (testimony of Dr. Flaten); DX 5630 (*Decker* ECF No. 246-24).) As of September 2, 2005, these symptoms were not diagnosed as NSF. (Trial Tr., Mar. 19, 2013, at 2796:9–19 (testimony of Dr. Feigal).)

As of September 2, 2005, Omniscan's labeling already warned of nearly all of the potential side effects these patients reportedly experienced. (DX5205 (*Decker* ECF No. 246-10); *supra* at 8-9.) Indeed, the only symptoms common to the four AERs already appeared in Omniscan's warnings: myalgia, arthralgia, pain, and kidney failure. (*Id.*)

F. The Association Between NSF and GBCAs

Following years of research and investigation by Dr. Cowper and others, the first suggestion of a possible association between NSF and GBCAs in patients with severe renal impairment came with electronic publication of a letter to the editor by Dr. Thomas Grobner, an Austrian nephrologist, in January 2006. (Trial Tr., Mar. 11, 2013, at 1333:22–1334:10 (testimony of Dr. Semelka) (discussing T. Grobner, *Gadolinium—A Specific Trigger for the Development of Nephrogenic Fibrosing Dermopathy and Nephrogenic Systemic Fibrosis?*, 21 NEPHROLOGY DIALYSIS TRANSPLANTATION 1104 (2006)) (attached as Ex. 6).) This news blind-sided the medical and scientific community. (*See, e.g.*, Trial Tr., Mar. 15, 2013, at 2314:11–17 (testimony of Dr. Weisbord).) In response, GEHC issued "Dear Doctor Letters" in June 2006 and December 2006 warning about an association between Omniscan and NSF (Trial Tr., Mar. 14, 2013, at 2202:6–19 (testimony of Dr. Cohan); DX 5277 (*Decker* ECF No. 246-15); DX 5359 (*Decker* ECF No. 246-17)), and FDA issued public health advisories in June 2006 and December 2006 (Trial Tr., Mar. 11, 2013 at 1344:7–1345:17 (testimony of Dr. Semelka); DX 5287 (*Decker* ECF No. 246-16) (PAGEID# 19544).)

G. Mr. Decker's NSF Diagnosis

In March 2009, Mr. Decker complained to Dr. Zafar Magsi, his treating nephrologist at the time, of skin hardening in his legs and difficulty walking. (Trial Tr., Mar. 18, 2013, at 2473:24–2474:7 (testimony of Dr. Magsi); DX7000A, Tab 17 (*Decker* ECF No. 247-10

(PAGEID# 20319).) For these symptoms, Dr. Magsi referred Mr. Decker to a rheumatologist, Dr. Michael Lindamood, who diagnosed Mr. Decker with scleroderma, an autoimmune disease characterized by hardening of the skin that NSF closely resembles. (Trial Tr., Mar. 18, 2013, at 2486:3–7 (testimony of Dr. Lindamood).) After being treated by Dr. Lindamood for approximately one year, Mr. Decker sought a second opinion from another rheumatologist, Dr. James Gideon, who diagnosed NSF in August/September 2010. (Trial Tr. at 1398:2–1399:22 (testimony of Dr. Gideon).)

H. The Verdict and the Trial Judge's Recusal from Post-Trial Proceedings Because He Determined He Could Not Be Fair and Impartial

On March 22, 2013, the jury returned its verdict, and the Court entered judgment on March 28, 2013. The next day, on March 29, 2013, Plaintiffs moved for prejudgment interest under Section 1343.03(C)(1) of the Ohio Revised Code. To obtain an award of prejudgment interest under that statute, Plaintiffs must prove both that they made good-faith settlement efforts before trial and that GEHC did not. *See Moskovitz v. Mt. Sinai Med. Ctr.*, 635 N.E.2d 331, 347 (Ohio 1994).

After Plaintiffs moved for prejudgment interest, the Court held a hearing by telephone on the motion on April 2, 2013. (*See* Memo. of Opinion and Order, Apr. 2, 2013 (*Decker* ECF No. 223).) During the hearing, the trial judge raised the prospect of recusal in response to Plaintiffs' motion. (Declaration of J. Fitzpatrick (Ex. 2), at 3.) Counsel for GEHC advised that the law does not require recusal because the Ohio prejudgment interest statute contemplates that a trial judge who is involved in settlement efforts will make the decision whether to award prejudgment interest based on his interactions with the parties. (*Id.* at 4.) Plaintiffs' counsel neither encouraged nor opposed recusal. (*Id.* at 5.) Until the telephonic hearing with the Court on April 2, no party had any reason to believe there was any basis for the trial judge to recuse himself.

(*See id.* at 7.) Further, the trial judge participated in no settlement discussions with the parties once the trial began on March 5, 2013. (Supp'l Declaration of M. O'Donnell (Ex. 4), at 5.)

Following the April 2 hearing, the Court entered an order stating that, if the case does not settle, "then the Court will recuse itself from ruling on the motion, as the Court might have to be a witness to the key factual issue: Whether Plaintiffs exercised good faith and Defendant failed to do so in trying to settle the case before trial." (Memo. of Opinion and Order, Apr. 2, 2013 (*Decker* ECF No. 223).) After conferring with Plaintiffs, GEHC filed a notice on April 5, 2013, reporting that Plaintiffs intended to proceed with their motion for prejudgment interest, requiring GEHC to oppose. The next business day, the trial judge entered an order recusing himself:

> As I told the parties during the April 2 teleconference, because I was so heavily involved in personally trying to mediate a settlement before trial, I do not think I can be fair and impartial in deciding whether either party negotiated in good faith, which will be the central issue in the motion for prejudgment interest. Further, it is possible I could become a witness.
>
> Therefore, by Monday, April 15, either the parties are to file a joint consent to have the matter transferred (not referred) to Magistrate Judge Kenneth McHargh or I will have the matter transferred by random draw to another district judge.

(Order of Recusal, Apr. 8, 2013 (*Decker* ECF No. 225), at 1.) Significantly, this order does not base recusal on concern for an "appearance" of partiality; rather, in the Order of Recusal, the trial judge recites that "I do not think I can be fair and impartial" when deciding whether either party engaged in settlement discussions in good faith. (*Id.*) On April 22, 2013, the trial judge ordered the clerk to assign Plaintiffs' motion for prejudgment interest to a new judge. (Order of Recusal and Reassignment, Apr. 22, 2013 (*Decker* ECF No. 269).) At that time, Plaintiffs' motion for prejudgment interest was the only contested matter pending before the Court.

GOVERNING LEGAL STANDARD

A court may grant a new trial under Rule 59(a) if the verdict is against the weight of the evidence, if the damages award is excessive, or if the trial was influenced by prejudice or bias, or otherwise unfair to the moving party. *Mike's Train House, Inc. v. Lionel LLC*, 472 F.3d 398, 405 (6th Cir. 2006). Where an evidentiary error "so altered the total mix of information submitted to the jury that it was substantially likely to have affected the verdict," a jury verdict should be vacated. *Stockman v. Oakcrest Dental Ctr., P.C.*, 480 F.3d 791, 804 (6th Cir. 2007) (citations omitted) (remanding for new trial where improper admission of prejudicial settlement letters were substantially likely to have affected the verdict); *Mike's Train House, Inc.*, 472 F.3d at 409–10 (remanding for new trial where improper admission of expert's testimony under *Daubert* "likely had a substantial effect on the verdict").

Alternatively, under Rule 59(e), a district court may alter or amend a judgment to correct a clear error of law, account for newly discovered evidence or an intervening change in the controlling law, or otherwise prevent manifest injustice. *Heil Co. v. Evanston Ins. Co.*, 690 F.3d 722, 728 (6th Cir. 2012) (citing *GenCorp, Inc. v. American Int'l Underwriters*, 178 F.3d 804, 834 (6th Cir. 1999)) (granting new trial).

ARGUMENT

I. The Court Should Grant a New Trial or Alter or Amend the Judgment on Plaintiffs' Failure to Warn Claim.

At trial, Plaintiffs identified two warnings that GEHC should have included on Omniscan's labeling or package insert: the results of studies regarding the symptoms from the four AERs and the retention of Omniscan in the body of patients with renal impairment. But Mr. Decker's doctors testified they do not consider those types of information to be clinically significant, particularly without an association between GBCAs and NSF, and would not have

changed their practice. In light of this testimony, there is no evidence from which the jury could find that GEHC's failure to warn proximately caused Mr. Decker's NSF. The Court should also order a new trial because of the substantial and unfair prejudice flowing from its decision to overrule GEHC's proffered jury instruction on the AERs that would have helped put what proved to be a key issue into its proper context. For these reasons, the Court should order a new trial or alter or amend the judgment on Plaintiffs' inadequate warning claim.

A. Plaintiffs Failed to Prove Warning Causation or to Identify a Warning GEHC Failed to Give.

Ohio's statute on inadequate warning claims expressly premises liability on the specific warning the defendant should have provided to prevent the injury at issue. Whether the inadequate warning claim is based on post-marketing warnings or on warnings at the time of marketing, a finding of liability requires identification of "*the* warning" or "*the* post-marketing warning" of a reasonable manufacturer. Ohio Rev. Code § 2307.76(A)(1)(b) & (A)(2)(b) (emphasis added). Therefore, a plaintiff must both identify the warning that should have been given and show that the warning would have prevented the injury. *See, e.g.*, *Miller v. Alza Corp*., 759 F. Supp. 2d 929, 934–35 (S.D. Ohio 2010) ("[T]he Court finds it necessary to identify the warnings Plaintiff argues should have been given to fully, properly and adequately warn of foreseeable risks."). In this respect, Ohio law follows other jurisdictions that require evidence of the specific warning that would have prevented the harm.[4]

[4] *See, e.g.*, *Bourelle v. Crown Equip. Corp*., 220 F.3d 532, 539 (7th Cir. 2000) (affirming summary judgment because the expert's "failure to even draft a proposed alternative warning . . . renders his opinion regarding the alleged inadequacy of Crown's existing warning . . . unreliable."); *Workman v. AB Electrolux Corp*., No. 03-4195-JAR, 2005 U.S. Dist. LEXIS 16306, at *54 (D. Kan. Aug. 8, 2005) (granting summary judgment on failure to warn claim because "plaintiffs fail to identify any warnings that would have prevented the fire"); *Howard v. Digital Equip. Corp*., C.A. No. 95-905, 1998 U.S. Dist. LEXIS 18795, at *13 (E.D. Pa. Nov. 25, 1998) (granting summary judgment where "plaintiff never even identifies just what warning should have been placed on the LK401 keyboard or how a warning would have prevented her injuries").

At trial, Plaintiffs failed to present evidence to carry their burden of proving that the warnings at issued proximately caused Mr. Decker's NSF. Plaintiffs presented no evidence that different warnings would have prevented Mr. Decker from receiving a GBCA other than Omniscan, and Plaintiffs' own expert conceded at trial that these other GBCAs have been associated with cases of NSF in any event. (Trial Tr., Mar. 13, 2013, at 1842:13–23 & 1871:11–25 (testimony of Dr. Fine).) Any additional warnings Dr. Blume proposed and Plaintiffs argued would have failed to prevent Mr. Decker from receiving an administration of Omniscan. Therefore, Plaintiffs did not carry their burden of proving proximate causation.

1. The Evidence at Trial Showed That Plaintiffs' Additional Warnings Would Not Have Prevented Mr. Decker from Receiving Omniscan; Therefore, Plaintiffs Failed to Prove Proximate Cause.

At trial, Plaintiffs' evidence regarding what warnings GEHC should have given came from Cheryl D. Blume, Ph.D. She testified that Omniscan's labeling should have included two general types of information or warnings: (1) reporting the symptoms for each of the four patients described in the AERs, and (2) disclosing that in multiple studies of patients with impaired kidney function researchers were unable to recover all of the Omniscan administered. But the undisputed evidence at trial demonstrates that any such warnings would not have prevented Mr. Decker from receiving an administration of Omniscan in 2005. *See Miller*, 759 F. Supp. 2d at 935–36; *In re Norplant Contraceptive Prods. Liab. Litig. v. American Home Prods. Corp.*, 955 F. Supp. 700, 711 (E.D. Tex. 1997) ("Plaintiffs have the burden of proving that a different warning would have changed the decision of the treating physicians.").

Mr. Decker's doctors testified that the warning needed to prevent Mr. Decker's NSF was the *association* between Omniscan and NSF in the medical literature, which did not come until 2006—at least four months *after* Mr. Decker's Omniscan administration. Both Dr. Phillip

Shaffer (Mr. Decker's treating radiologist) and Dr. Geoffrey Wiot (Dr. Shaffer's partner and head of MR for the practice, who made decisions about the policies and procedures about GBCA use, including which GBCA to use) testified that warnings about gadolinium retention or adverse event reports, the warnings urged by Dr. Blume, would *not* have changed their practices in 2005 before an association between GBCAs and NSF was first identified. Even Dr. Blume did not opine that GEHC could have warned of NSF in 2005—before its first reported association with GBCAs in 2006. Without that evidence, Plaintiffs failed to carry their burden of proof.

a. The Evidence Shows Mr. Decker's Doctors Would Not Have Changed Their Practices Before an Association between Omniscan and NSF.

Plaintiffs did not carry their burden of proving that any failure to warn was the proximate cause of Mr. Decker's injuries. Indeed, the trial record demonstrates a complete failure of proof on this point. Mr. Decker's treating radiologist was Dr. Phillip Shaffer, who ordered Mr. Decker's MR procedure on September 2, 2005 during which Omniscan was administered. (Trial. Tr., Mar. 11, 2013, at 1093:1–16 (testimony of Dr. Shaffer).) Dr. Shaffer testified that the decisions about which GBCAs should be purchased and what procedures should apply to the use of GBCAs in his radiology practice were made by his partner, Dr. Geoffrey Wiot. (*Id.* at 1095:7-17; 1113:14–1114:10.) Dr. Wiot testified that he did not consider that retention of Omniscan was clinically significant in the absence of an association with NSF, the clinical safety profile of Omniscan mattered more to him than GEHC's representations about the product, and use of Omniscan remained the standard of care even in patients with severe kidney impairment long after the association between NSF and Omniscan. (Trial Tr., Mar. 11, 2013, at 1156:10–1157:4, 1101:24–1102:23, 1137:9–1138:3 & 1169:23–1172:4 (testimony of Dr. Wiot).) Because Omniscan is a prescription drug administered by doctors, Ohio law requires that GEHC warn the

prescribing doctors, not Mr. Decker himself. (Trial Tr., Mar. 20, 2013, at 2980:10–17 (final jury charge).)

In connection with his role in making decisions about which GBCAs to use and the policies and procedures for their use, Dr. Wiot testified that he and his radiology group "place[d] more trust on other members in the profession to see what—how they are handling certain situations" than on small numbers of adverse events or warnings from a product's manufacturer. (Trial Tr., Mar. 11, 2013, at 1101:24–1102:1 (testimony of Dr. Wiot).) Dr. Shaffer agreed. (Trial Tr., Mar. 11, 2013, at 1101:24–1102:1 (testimony of Dr. Shaffer); *id*. at 1131:25–1132:3; *id*. at 1102:20–23 (expressing skepticism of safety communications from a manufacturer "particularly if it's the first time you've heard of a particular problem.").) This was particularly the case where administering a GBCA was the standard of care at the time, as it was for the type of MR procedure Mr. Decker had with Omniscan on September 2, 2005. (*Id.* at 1111:25–1112:4.)

When questioned whether various facts would have mattered in making safety decisions about which GBCAs to use, Dr. Wiot made clear that the key information he needed was the association with NSF, which was first identified in 2006. For example, Dr. Wiot testified unambiguously that information about the retention of Omniscan would *not* have made any difference to him absent an identified association between GBCAs and NSF, which first occurred in 2006, *after* Mr. Decker's administration of Omniscan:

> Q. If GE knew as early as 1995 that its own clinical trials in patients with kidney disease showed that they were losing 26 percent of the gadolinium after administration, that it was not being accounted for in excretion [Dr. Blume's theory for warning], is that information that you would have liked to have had, Doctor?

> A. Think in the—not knowing anything else about what that would mean to me, I don't know if it would make a difference to me. **Knowing that gadolinium floating around in the system afterwards, or being stored someplace in the renal patients is causing NSF, then, yes, it would be important to me.** ***But not knowing about NSF, not knowing about the relationship, it would have made no difference to me.***

(Trial Tr., Mar. 11, 2013, at 1156:10–22 (testimony of Dr. Wiot) (emphasis added).) Under repeated questioning, Dr. Wiot stood firm that the retention of Omniscan would only worry him if an association with the risk of NSF were known:

> Q. And if the internal scientists at GE were concerned about the fact that they could not account for over a quarter of the amount of gadolinium being excreted because of safety concerns, is that something that you would like to know?
>
> A. Again, it would be in relationship to knowing about NSF.

(*Id*. at 1156:23–1157:4; *see also id*. at 1166:22–1167:5 (disassociation of Omniscan in animal studies only relevant once an association with NSF is known); *id*. at 1164:19–1165:2 (same).)[5] Dr. Shaffer agreed with Dr. Wiot that the retention of Omniscan was unimportant without knowing about an association with NSF. (Trial Tr., Mar. 11, 2013, at 1105:16–20 (testimony of Dr. Shaffer) ("It would be interesting to know, but I would again need to know if that meant anything. . . . If it meant anything in the sense of is it harmful or is it irrelevant.").)

Where the physician responsible for administration of a prescription drug would not have changed his practices with what the plaintiff claims is an adequate warning, the defendants' inadequate warnings cannot proximately cause the harm. *See, e.g.*, *Seley v. G.D. Searle & Co*.,

[5] The renal studies that Dr. Blume testified GEHC should have warned about through the labeling or a "Dear Doctor Letter" were published in the medical literature (Trial Tr., Mar. 11, at 1324:11–15 (testimony of Dr. Semelka); Trial Tr., Mar. 19, at 2676:10–22 (testimony of Hugo Flaten); Trial Tr., Mar. 19, at 2771:16–19 (testimony of Dr. Feigal)), which Dr. Wiot was following (Trial Tr., Mar. 11, 2013, at 1147:18–20 (testimony of Dr. Wiot)).

423 N.E.2d 831, 838–40 (Ohio 1981) ("[A]n adequate warning would have made no difference in the physician's decision" and so "the required element of proximate cause between the warning and ingestion of the drug is lacking."); *Ackermann v. Wyeth Pharm.*, 526 F.3d 203, 209–12, 213 (5th Cir. 2008) (prescribing physician testified that he would have prescribed the drug regardless of whether he received the proposed stronger warning).

As in *Seley* and *Ackermann*, Mr. Decker's physicians testified warnings of the type proposed by Plaintiffs would not have influenced the standard of care or their practices for administration of Omniscan until the association between GBCAs and NSF was first proposed in 2006. Plaintiffs presented no other evidence to the contrary. Therefore, the evidence at trial shows that inadequate warnings cannot proximately cause Mr. Decker's NSF. *See Vanderwerf v. SmithKlineBeecham Corp.*, 529 F. Supp. 2d 1294, 1309–11 (D. Kan. 2008) (no causation where doctors said that more extensive warnings would not have changed their decisions to prescribe the drug).

b. Because Mr. Decker's Doctors Did Not Read the Labeling or "Dear Doctor Letters," Plaintiffs Did Not Carry Their Burden.

Plaintiffs' inadequate warning claim fails for the additional reason that Mr. Decker would have received Omniscan on September 2, 2005 even if GEHC had given a different warning. *See Miller*, 759 F. Supp. 2d at 936 ("A plaintiff . . . 'must establish the existence of proximate cause between the [product] and the fact of the plaintiff's injury.'") (quoting *Hisrich v. Volvo Cars of N. Am., Inc.*, 226 F.3d 445, 450–51 (6th Cir. 2000)). Under Ohio law, proving proximate cause requires that the plaintiff prove that the "lack of adequate warnings contributed to the plaintiff's [use of the product]." *Hisrich*, 226 F.3d at 451.

Dr. Shaffer, Mr. Decker's treating radiologist who has been practicing for over 30 years, testified that the labeling was something "[n]ormally you read that the first time you use it, or the

second time, and you know what's there generally, but after that—you know, you use the medicine on a daily basis. You do not read it every time you use it." (Trial Tr., Mar. 11, 2013, at 1109:1–6 & 1101:3–6 (testimony of Dr. Shaffer).) Dr. Wiot, who set the policies and procedures for use of GBCAs in his radiology practice with Dr. Shaffer, testified that he paid little attention to information from vendors, like GEHC. (Trial Tr., Mar. 11, 2013, at 1133:19–21 (testimony of Dr. Wiot).) Dr. Wiot gave information from manufacturers such little regard that he may simply have thrown away GEHC's June 2006 "Dear Doctor Letter." (*Id.* ("I receive so much mail from so many vendors that I may very well have received it or not received it, or received it and filed it immediately.").) Instead, Dr. Wiot attached greater importance to his experience with years of safe clinical use of Omniscan. (*Id.* at 1124:7–23, 1126:17–1127:6.) Plaintiffs presented no contrary evidence that Mr. Decker's physicians would have read additional warnings or information on Omniscan's labeling.

Under Ohio law, evidence that a warning is not read defeats proximate causation. *See, e.g.*, *Phan v. Presrite Corp.*, 653 N.E.2d 708, 711 (Ohio Ct. App. 1994) ("Even if the additional warnings . . . were given, they would not have prevented the injuries because neither [physician] read the warning . . . ."). "[W]here the evidence demonstrates that an adequate warning would have made no difference in the physician's decision as to whether to prescribe a drug . . . the required element of proximate cause between the warning and ingestion of the drug is lacking." *Miller*, 759 F. Supp. 2d at 936 (quotation omitted). Accordingly, the evidence shows that Plaintiffs' did not carry their burden to prove warning causation.

2. At Trial, Plaintiffs Did Not Identify Warnings That Would Have Prevented Mr. Decker's Injuries.

Identification of the warning that should have been given "[is] indispensable to a rational conclusion that the product was . . . unreasonably dangerous to the user without warnings."

Morgen v. Ford Motor Co., 797 N.E.2d 1146, 1152 (Ind. 2003). Without such evidence, the jury cannot determine whether an alternative warning would have prevented the injury for the simple reason that the jury cannot know what the alternative warning should have said without evidence on the issue. *Phillips v. Raymond Corp*., No. 99 C 2152, 2006 U.S. Dist. LEXIS 27632, at *20–21 (N.D. Ill. Apr. 25, 2006) ("[N]o rational jury could find Defendant liable on a failure to warn theory" where the plaintiff "failed to suggest a different warning that would be adequate . . . and has failed to identify a warning that would have . . . prevented the injury.").

Plaintiffs did not identify any specific or additional warning that GEHC could have given that would have prevented Mr. Decker from receiving an administration of Omniscan, let alone would have prevented him from developing NSF. On this issue, the only testimony Plaintiffs presented came from their retained regulatory expert, Dr. Blume, who gave her opinion that the Omniscan labeling should have included two general types of information or warnings. First, Dr. Blume opined that the Omniscan labeling or package insert should have disclosed that multiple studies of patients with impaired kidney function showed that researchers were "unable, despite various efforts, to recover all of the administered drug." (Trial Tr., Mar. 12, 2013, at 1578:9–18 (testimony of C. Blume, Ph.D.); *see* also *id*. at 1579 ("[T]hey should have noted the—the conclusions from the study that they were unable to recover all of it.").)

In her opinion, placing this retention data from the renal studies on the labeling would show physicians the potential for "serious consequences to various organ systems." (*Id*. at 1582:23–25.) Of course, Plaintiffs never alleged injury to "various organ systems," instead seeking to recover for joint contractures, skin thickening, and other symptoms of NSF. Moreover, as discussed earlier, Dr. Wiot testified that information about the retention of Omniscan would not have made any difference absent the association between GBCAs and NSF,

which did not occur until after Mr. Decker received Omniscan. (Trial Tr., Mar. 11, 2013, at 1156:10–22 (testimony of Dr. Wiot) ("[N]ot knowing about NSF, not knowing about the relationship, it would have made no difference to me.").)

Second, Dr. Blume testified that the Omniscan labeling should have listed the symptoms reported for each of four patients described in the AERs. Specifically, she testified that the labeling should have noted the potential for "skin events," death, and diminished mobility and use of limbs. (Trial Tr., Mar. 12, 2013, at 1580:4–16 (testimony of C. Blume, Ph.D.); *see also id*. at 1586:15–17 ("[T]he labeling should have been updated to reflect this information in these patients."); 1567:17–19 ("[T]he patients would certainly have been summarized along with earlier information that was accumulated by the company as well from other studies.").[6]) She also opined that GEHC's predecessor should have brought these symptoms to the attention of the medical community through a "Dear Doctor Letter" as early as 2004. (*Id*. at 1567:13–19.) No other witness testified that the Omniscan labeling or a "Dear Doctor Letter" could have or should have contained any other information or warnings as of the date of Mr. Decker's Omniscan administration on September 2, 2005.

In their closing argument, Plaintiffs relied on Dr. Blume's testimony to argue that GEHC should have warned about the four AERs and the results of the renal studies showing the amount of Omniscan retained in the bodies of kidney patients:

> Was there failure to warn? Remember, Dr. Blume talked about warnings? She worked for pharmaceutical companies and

[6] Dr. Blume also argued that GEHC should have contraindicated Omniscan in patients with severe renal failure in 2005 (Trial Tr. at 1579:15-1580:16), but this opinion was rejected by the jury's decision on Plaintiffs' other two liability theories, design defect and nonconformance. This opinion also incorrectly relies on AERs to determine causation. *See, e.g., McClain v. Metabolife Intern., Inc*., 401 F.3d 1233, 1250 (11th Cir. 2005) ("Uncontrolled anecdotal information [from AERs] offers one of the least reliable sources to justify opinions about both general and individual causation"); *Honeyman v. Hoyt (In Re Carter-Wallace Sec. Litig.)*, 220 F.3d 36, 42 (2d Cir. 2000) ("Here, the early medical reports may have indicated a potential problem, but until a connection between Felbatol and any illness could be made, we would not expect Carter-Wallace to abandon its product on what, at the time, would have been speculation.").

> continues to do so today. She told you there are ways to warn, "Dear Doctor" letters, label. She said you need to add the pharmacokinetic studies, you need to tell doctors what you know. You need to tell them is there a risk in the specific population of renally-impaired patients; death, hospitalization, disability, skin pain, all those kinds of things.

(Trial Tr., Mar. 20, 2013, at 3014:24–3015:7.) Plaintiffs offered no other basis to support their failure to warn claim.

But each of the warnings identified by Dr. Blume that Plaintiffs argued should have been included on the Omniscan labeling or disseminated through a "Dear Doctor Letter" *was already included on the Omniscan labeling* as of December 2004—some nine months before Mr. Decker's Omniscan administration on September 2, 2005:

What Dr. Blume opined GEHC should have warned about	**Warnings actually on the Omniscan labeling as of December 2004** (DX 5205)
"[G]adolinium toxicity in patients with compromised or decreased renal failure." (Trial Tr., Mar. 12, 2013, at 1484:19–20.) "[I]n patients with renal compromise, with severe renal compromise . . . [gadolinium toxicity] can have serious consequences to various organ systems." (*Id*. at 1582:8–9.)	"This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function." "Caution should be exercised in patients with impaired renal insufficiency."
"[P]ersistent myalgia." (*Id*. at 1555:22.) "The myalgia moved into arthralgia." (*Id*. at 1557:12.)	"Arthalgia, myalgia."
"[A]ggravation of pre-existing renal insufficiency." (*Id*. at 1555:23.)	"Acute reversible renal failure." "Abnormal hepatic function."
"[P]ain of skin, pain of joints." (*Id*. at 1557:13.) "[S]evere muscle pains, and one having palpitations." (*Id*. at 1574:14–15.)	"Arthalgia, myalgia," "pain," "chest pain," "abdominal pain."

"[T]his patient is experiencing a severe reaction." (*Id*. at 1570:9–10.) "Death." (*Id*. at 1580:13–14.)	"[S]erious, life threatening, fatal anaphylactoid or cardiovascular reactions or other idiosyncratic reactions . . . especially in those patients with a known clinical hypersensitivity." "Death."
"[S]kin events, including induration." (*Id*. at 1572:10–11, 1580:12.) "[D]iminished mobility and diminished use of their limbs." (*Id*. at 1580:15–16.)	"Skin and Appendage Disorders: Pruritus, rash, erythematous rash, skin discoloration, sweating increased, urticaria."

This information on the Omniscan labeling before Mr. Decker received Omniscan provides the warnings Plaintiffs argued to the jury that GEHC should have given. Accordingly, they cannot be the basis of liability, entitling GEHC to a new trial or alteration or amendment of the judgment. *Reece v. Astrazeneca Pharms., LP*, 500 F. Supp. 2d 736, 749–50 (S.D. Ohio 2007) (granting summary judgment where the label "warned of th[e] risk on the Crestor label in no uncertain terms").

B. The Court's Failure to Instruct the Jury on the Limits of Adverse Event Reports Unfairly Prejudiced GEHC's Defense.

The need for a new trial is underscored by the Court's error in rejecting GEHC's proffered AER instruction—which was requested to help place the lynchpin of Plaintiffs' warnings case into its proper legal context. (Trial Tr., Mar. 19, 2013, at 2939:18–2940:1.) Because of the limited value and potential for misuse and confusion presented by evidence of AERs, courts regularly give limiting instructions. Indeed, the Court determined that such an instruction should be given here, but changed its mind after the final pretrial conference. Failure to give a proper limiting instruction caused undue and substantial prejudice to GEHC on the evidence at the heart of Plaintiffs' warnings case, permitting misuse of the AER evidence.

1. Courts Recognize That AERs Cannot Prove Causation and Regularly Instruct Juries on the Limits of Their Weight and Significance.

AERs are nothing more than "complaints called in by product consumers without any medical controls or scientific assessment." *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1250 (11th Cir. 2005). The Supreme Court explains that "[a]dverse event reports are daily events in the pharmaceutical industry; in 2009, the FDA entered nearly 500,000 such reports into its reporting system." *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309, 1321 (2011).

Not surprisingly, a multitude of courts (including this one) have cautioned that AERs have, at best, limited usefulness at trial. *See In re Meridia Prods. Liab. Litig.*, 328 F. Supp.2d 791, 807 (N.D. Ohio 2004) (Gwin, J.) ("Even readers with only a casual understanding of statistics can recognize that this evidence does not speak to the issue of causation."); *see also Rhodes v. Bayer Healthcare Pharms.*, No. 10-1695, 2013 U.S. Dist. LEXIS 44670, at *14–15 (W.D. La. Mar. 26, 2013) ("Dr. Hamilton's reliance on adverse event reports is also unimpressive, as such reports do not demonstrate the requisite degree of reliability demanded by *Daubert*."); *Gibson v. Sanofi-Aventis U.S., LLC*, No. 3:07CV-192-S, 2009 U.S. Dist. LEXIS 102864, at *17 (W.D. Ky. Oct. 27, 2009) (a "collection of case reports" is a "wholly inadequate" for an expert opinion on what warning should have been given); *Wade-Greaux v. Whitehall Labs., Inc.*, 874 F. Supp. 1441, 1481 (D.V.I. 1994) ("[S]uch data represent anecdotal information of chance associations, do not purport to assess cause and effect and have no epidemiological significance."). Because of these limitations, "adverse event reports are admissible only to prove when [the defendant] had notice of the adverse events alleged therein." *Graves v. Merck & Co. (In re Fosamax Prods. Liab. Litig.)*, 1:06-MD-1789-JFK, No. 1:06-cv-5513-JFK, 2010 U.S. Dist. LEXIS 114262, at *7–8 (S.D.N.Y. Oct. 27, 2010).

As the Court recognized, juries, which have not heard of AERs before, will not understand their limitations unless explained to them. (*See* Final Pretrial Tr., Feb. 21, 2013 (Ex. 7), at 42:24–43:1 ("I didn't know what an AER was before I had this MDL so I doubt if any juror would know what it is.").) Recognizing this lack of familiarity by juries and the potential for confusion resulting from use of AERs for improper purposes, courts regularly include instructions explaining the limitations of AERs. *See, e.g.*, *Schedin v. Ortho-Mcneil-Janssen Pharms., Inc*., 808 F. Supp. 2d 1125, 1139 (D. Minn. 2011) (detailing limiting instruction on AERs); *Bartlett v. Mut. Pharm. Co*., No. 08-cv-358, 2010 U.S. Dist. LEXIS 111259, at *2 (D.N.H. 2010) (if admitting AERs is proper, the defendant "may request a limiting instruction and/or seek other limits on their use (e.g., to require redactions, or allow only summaries rather than the reports themselves) to prevent any unfair prejudice"); *Meyerson v. Walgreen Co*., No.05-60025-CIV, 2006 U.S. Dist. LEXIS 97267, at *20 (S.D. Fla. May 18, 2006) (noting that the defendant can "address the limited probative value of AERs through . . . a limiting instruction from the Court").

2. The Court Recognized the Need for an AER Instruction, But Refused to Give One.

Consistent with this authority and the general practice of federal courts, the Court proposed to give an instruction on the AERs in an earlier NSF case (*Knase v. General Electric Company* (No. 1:08-gd-50026)), set for trial in January 2011 in the MDL. That case settled the day before the start of trial, after the Court had already ruled it would give a limiting instruction on the AERs. (Email from Court, Jan. 18, 2011 (Ex. 8), attachment at 14.) At Plaintiffs' request, the Court ruled that it would apply its orders from previous cases, including *Knase*, in *Decker*. (Tr. of Telephone Conference, Aug. 13, 2012 (Ex. 9), at 8.) During pretrial proceedings and at the final pretrial conference in this case, the Court again agreed that an instruction on AERs was

appropriate. (See Email from Court, Feb. 19, 2013 (Ex.10), draft Final Jury Charge at 22.) Accordingly, the Court proposed to give the following instruction identical to the one from *Knase*:

> You have also heard testimony and seen exhibits relating to "adverse event reports" (also known as "AERs"), including case reports, case series, spontaneous reports, and adverse events reporting injuries in person who have been administered Omniscan. AERs only provide notice to a manufacturer that a negative reaction occurred around the time that a drug was administered; they do not prove that the reaction was actually a side effect or caused by the drug administration.

(*Id.*; *see also* Final Pretrial Tr., Feb. 21, 2013 (Ex. 7), at 43:6–7 ("I'm going to leave it in the final instruction."); *id*. at 44:21–22 ("I'm going to give this instruction on AERs the way it is.").)

On its own initiative the next day, February 22, 2013, the Court reversed course and indicated it would not give the AER instruction after all. (*See* Email from Court, Feb. 22, 2013 (Ex.11).) The Court provided the following explanation:

> Upon further review and consideration, Judge Polster has decided to delete the Adverse Event Reports instruction from the Final Jury Charge. The instruction singles out one type of evidence, and adds, rather than minimizes, confusion. An AER tells a drug manufacturer that a negative reaction occurs around the time the drug was administered. An AER does not, in and of itself, prove that the negative reaction was caused by the drug.

(*Id.*) At the charging conference, the Court adhered to this position, over GEHC's objection, and refused to give the instruction. (Trial Tr., Mar. 19, 2013, at 2939:18–2940:22 (charging conference); *see also* Defendants' Objections to Jury Instructions, Mar. 18, 2013 (*Decker* ECF No. 208), at 1–3 (requesting limiting instruction).)

One reason the Court provided for refusing to give the instruction was that no witness testified that Omniscan caused the symptoms described in the AERs:

> I don't think anyone, no witness has testified that you can use an AER to show that Omniscan caused any illness or medical condition described in those AERs and besides, it doesn't matter because those patients are not—are not the plaintiffs.

(Trial Tr., Mar. 19, 2013, at 2940:9–13 (charging conference).) To the contrary, Plaintiffs repeatedly and emphatically emphasized for the jury that Omniscan caused the conditions reported in the AERs and that Mr. Decker suffered from the same symptoms. (*See, e.g.*, Trial Tr., Mar. 12, 2013, at 1484:10–20, 1537:18–24 (testimony of C. Blume, Ph.D.).) In fact, based on this evidence, Plaintiffs went so far as to claim that GEHC was on notice of information about which they should have warned. For example, Dr. Blume testified that GEHC should have known to *contraindicate* Omniscan in 2005—a step FDA did not take until 2009, more than three years following the association between NSF and GBCAs—based only on the symptoms in the four AERs and the renal studies. (Trial Tr., Mar. 12, 2013, at 1579:15–1580:16, 1653:3 (testimony of C. Blume, Ph.D.); P1_2348 (*Decker* ECF No. 245-2).) In this way, Plaintiffs made the AERs the lynchpin of their warnings case.

3. The Court's Failure to Give a Limiting Instruction on the AERs Was Not Harmless Error.

Not only was the Court's basis for refusing to give an instruction on the AERs inconsistent with the evidence at trial (and, in fact, the central thrust of Plaintiffs' liability case[7]), the Court's rationale shows the prejudice and the need for the instruction in the first place: "[T]hose patients are not—are not the plaintiffs." (Trial Tr., Mar. 19, 2013, at 2940:12–13 (charging conference).) Plaintiffs' closing argument confirms the centrality of the AERs to proving their inadequate warning claim. As just one example, Plaintiffs argued that the symptoms from the AERs were key facts that should have been communicated on Omniscan's

labeling: "You need to tell them[,] is there a risk in the specific population of renally-impaired patients; death, hospitalization, disability, skin pain, all those kinds of things." (Trial Tr., Mar. 20, 2013, at 3015:4–6 (closing argument).)

The Court's refusal to give an instruction on the legal significance of the AERs left the jury with a misleading and one-sided picture the importance of the four AERs in this case. It also permitted Plaintiffs to give undue and improper weight and influence to the AERs in their deliberations. Because those AERs were the crux of Plaintiffs' failure to warn claim, it is impossible to "say, with fair assurance, . . . that the judgment was not substantially swayed by the error" of rejecting the instruction. *Tamraz v. Lincoln Elec. Co.*, 620 F. 3d 665, 676 (6th Cir. 2010). Indeed, the jury's defense verdict on Plaintiffs' other two causes of action (design defect and non-conformance to representations) underscores prejudice to GEHC of the Court's error in failing to provide a proper instruction on the AERs. Therefore, the Court should grant a new trial on Plaintiffs' inadequate warning claim.

C. Admission of Evidence That a Foreign Governmental Authority Determined Omniscan Caused the Second AER Was Unfairly Prejudicial to GEHC.

Throughout trial, the Court allowed Plaintiffs—over GEHC's objections—to present significant, prejudicial testimony that a foreign governmental authority, Denmark's Patient Insurance Association ("PIA"), determined that Omniscan caused the symptoms reported in the second AER, involving Birthe Madsen. The PIA administers a patient compensation award system, which makes payment to patients who experience serious side effects from medications approved by the Danish Medicines Agency, Denmark's equivalent of the FDA. (*See generally* Trial Tr., Mar. 8, 2013, at 844–854, 931–39 & 1044–58 (testimony of Dr. Flaten, Ms. Lihaug,

[7] Indeed, the jury heard as much or more about Birthe Madsen, the subject of the second AER, than about Mr. Decker. (Trial Tr., Mar. 20, 2013 at 3049:8–20 ("We heard more about Birthe Madsen than we heard about poor Mr. Decker. We heard hours of Birthe Madsen.") (closing argument).)

and Dr. Rode discussing the PIA).) Witnesses at trial repeatedly testified that the PIA determined that Omniscan caused Ms. Madsen's symptoms and awarded her family damages after her death. In one day alone, three different witnesses, Dr. Hugo Flaten (GEHC's global head of pharmacovigilence at the time who had overall responsibility within the company for monitoring clinical experience with Omniscan), Elin Lihaug (who processed AERs and other pharmacovigilence and data in Denmark for GEHC), and Dr. Gert Rode (head of GEHC's medical division) each testified regarding the facts of Ms. Madsen's Omniscan administration, symptoms, death, and the processing of Ms. Madsen's claim by the PIA. (*See, e.g.*, Trial Tr., Mar. 8, 2013, at 844:18–845:15 (testimony of Dr. Flaten); *id.* at 935:19–936:11 (testimony of Ms. Lihaug); *id.* at 1045:2–23 (testimony of Dr. Rode).) In a fairly typical exchange, Ms. Lihaug testified, for example:

> Q. And in fact, [Birthe Madsen's] reaction was so severe that the Danish Government [through the PIA] had decided to award Mrs. Madsen's family money for that severe reaction that they found was caused by Omniscan, right?
>
> A. That's correct.

(Trial Tr., Mar. 8, 2013, at 934:22–935:1 (testimony of Ms. Lihaug).)

The testimony and documents about the PIA were unfairly prejudicial to GEHC because the PIA operates a "no-fault" award system unlike any no-fault insurance program with which jurors may have familiarity in their experience. Through this testimony, the Court permitted Plaintiffs to try the case of a Danish citizen within Mr. Decker's case, portray the PIA's decision to award compensation to Ms. Madsen's family for injuries resulting from an acute hypersensitivity or anaphylactic reaction to Omniscan as a finding of liability tantamount to that made by a judge or jury in the U.S. system of justice, inform the jury that the PIA paid

compensation to Ms. Madsen's family, then invite the jury to do the same by comparing Ms. Madsen's reaction to Omniscan to that of Mr. Decker.

The Court should have excluded that evidence as unfairly prejudicial. Courts routinely exclude evidence of foreign governmental actions. *See, e.g.*, *Pennsylvania Trust Co. v. Dorel Juvenile Group, Inc.*, 851 F. Supp. 2d 831, 842–43 (E.D. Pa. 2011) (excluding testimony of defendant's obligations under Canadian law as "inherently prejudicial" and creating a "substantial risk of jury confusion"); *In re Seroquel Prods. Liab. Litig.*, 601 F.Supp. 2d 1313, 1318, 1319 (M.D. Fla. 2009) (finding that any probative value of evidence of foreign labels and foreign regulatory actions is outweighed by the high probability of jury confusion); *accord In re Baycol Prods. Liab. Litig.* 532 F.Supp. 2d 1029, 1054 (D. Minn. 2007). Similarly, courts also exclude evidence of prior lawsuits. *See, e.g.*, *McLeod v. Parsons Corp.*, 73 F. App'x 846 (6th Cir. Sept. 5, 2003) (excluding evidence of other lawsuits involving the defendant as unfairly prejudicial); *Ross v. American Red Cross*, No. 2:09-cv-00905-GLF-MRA, 2012 U.S. Dist. LEXIS 77475, at *16–17 (S.D. Ohio June 5, 2012) (excluding evidence of other lawsuits involving defendants); *Newark Group, Inc. v. Sauter*, No. C2:01-CV-1247, 2004 U.S. Dist. LEXIS 31334, at *2 (S.D. Ohio Mar. 26, 2004) (excluding evidence of a prior lawsuit involving the parties).

Here, the Court's failure to exclude the PIA damages award was not harmless. The jury repeatedly heard that another entity, the PIA, had concluded under their system that Omniscan was responsible for Ms. Madsen's injuries. (*See, e.g.*, Trial Tr., Mar. 8, 2013, at 844:18–845:15 (testimony of Dr. Flaten); *id.* at 935:19–936:11 (testimony of Ms. Lihaug); *id.* at 1045:2–23 (testimony of Mr. Rode).) Dr. Blume repeatedly testified that the PIA "concluded gadolinium was the cause of [Birthe Madsen's] reaction." (*See* Trial Tr., Mar. 12, 2013, 1647:23:1649:9

(testimony of C. Blume, Ph.D.).) Plaintiffs used the PIA's no-fault conclusion that Omniscan caused Ms. Madsen's symptoms to show that GEHC should have known the Omniscan was the cause of these side effects. This cumulative testimony is, therefore, not harmless error; it goes to the heart of Plaintiffs' failure to warn claim. Where an evidentiary error "so altered the total mix of information submitted to the jury that it was substantially likely to have affected the verdict," a new trial is warranted. *Stockman*, 480 F.3d at 804 (citations omitted) (remanding for new trial where improper admission of prejudicial settlement letters were substantially likely to have affected the verdict). Therefore, the Court should grant a new trial.

II. The Trial Judge's Recusal Requires a New Trial to Avoid the Appearance of Partiality and to Maintain Public Confidence in the Administration of Justice.

In its leading case on recusal, the Supreme Court vacated a final judgment after trial that had been affirmed on appeal because of a disqualifying circumstance not appreciated by the district court judge at the time of the entry of judgment. *See Liljeberg v. Health Servs. Acquisition Corp.*, 486 U.S. 847, 855–56 (1988). The Supreme Court did so as a remedy for the original judge's failure to disqualify himself based on an appearance of partiality and to maintain public confidence in the judiciary. *Id.* at 866–67. The Court did not require a showing of actual bias. *Id.* at 850. Since *Liljeberg*, courts continue to set aside judgments solely because an appearance of partiality warranted recusal. *See, e.g.*, *Shell Oil Co. v. United States*, 672 F.3d 1283, 1294 (Fed. Cir. 2012); *United States v. Jordan*, 49 F.3d 152, 159 (5th Cir. 1995); *Preston v. United States*, 923 F.2d 731, 735 (9th Cir. 1991); *United States v. Kelly*, 888 F.2d 732, 747 (11th Cir. 1989).

In this case, the trial judge recused himself *sua sponte* from participation in deciding the only post-trial motion then pending because his involvement in pre-trial settlement discussions was so great that he did not think he could be fair and impartial in deciding Plaintiffs' motion for

prejudgment interest. (*See* Order of Recusal, Apr. 8, 2013 (*Decker* ECF No. 225), at 1.) Because his recusal was based on *pre-trial* conduct, the trial judge's post-trial recusal suggests that his own concerns about the appearance of fairness and impartiality should have counseled him to conclude that it was not wise for him to sit as the trial judge and to recuse pre-trial. For these reasons, as more fully explained below, a new trial is appropriate based on "the risk of injustice to the parties" and the "risk of undermining the public's confidence in the judicial process." *In re Aetna Cas. & Sur.*, 919 F.2d 1136, 1145–46 (6th Cir. 1990) (en banc).

A. Ohio and Federal Law Ordinarily Do Not Require Recusal Where the Trial Judge Is Involved in Pretrial Settlement Discussions.

Plaintiffs' motion for prejudgment interest did not require recusal in this case under state or federal law. Counsel for GEHC so advised the Court during the telephone conference on April 2, 2013. (Declaration of J. Fitzpatrick (Ex. 2), at 4.) Therefore, the trial judge's decision to recuse himself, prompted by Plaintiffs' motion for prejudgment interest, represents an extraordinary step that takes that decision outside the bounds of the law that typically would not only permit him to decide post-trial motions, but also require him to do so.

1. Ohio Law Contemplates That a Trial Judge Involved in Pretrial Settlement Discussions Will Decide a Motion for Prejudgment Interest.

Ohio's prejudgment interest statute seeks "to promote settlement efforts, to prevent parties who have engaged in tortious conduct from frivolously delaying the ultimate resolution of cases, and to encourage good faith efforts to settle controversies outside a trial setting." *Kalain v. Smith*, 495 N.E.2d 572, 573 (Ohio 1986). Therefore, the statute necessarily focuses on the good-faith settlement efforts of the parties *before trial*. *Bishop v. Munson Transp. (In re Solovan)*, 803 N.E.2d 821, 822 (Ohio 2003) (prejudgment interest "must be based on several factors that occur prior to trial"). In deciding on the parties' good-faith, pre-trial settlement

efforts, the statute contemplates that the trial judge will decide whether the parties acted in good faith based on his own experience and interactions with them. *See Gibbons v. Bair Found.*, No. 5:04-cv-2018, 2006 U.S. Dist. LEXIS 49596, at *8 (N.D. Ohio July 18, 2006) (Boyko, J.) ("The Court finds Plaintiffs are not entitled to prejudgment interest as a matter of law. The Court was aware of, and presided over, settlement discussions in which Defendant made good faith efforts to settle the case as reflected in the offers made.").

Moreover, case law under Ohio's prejudgment interest statute provides that a trial judge does not need to recuse himself from deciding a motion for prejudgment interest solely because he was involved in settlement efforts. *See, e.g.*, *Singer v. Celina Group*, No. 94 CA 0333, 1995 Ohio App. LEXIS 3690, at *6–7 (Ohio Ct. App. May 30, 1995) ("The very nature of R.C. 1343.03(C) implies that the judge of the merit trial will make the determination of prejudgment interest."). "Based upon the language of the statute, 'a judge' in a civil case is permitted to use his or her own experience with the case . . . to render a decision on prejudgment interest." *Id.*; *Freudeman v. Landing of Canton*, No. 5:09-cv-175, 2011 U.S. Dist. LEXIS 150023, at *23 (N.D. Ohio Dec. 30, 2011) (Dowd, J.) (noting that "the Court is so thoroughly familiar with this case" that no hearing is necessary on the motion). Indeed, counsel's research under Ohio's prejudgment interest statute has not located any case where the trial judge recused due to involvement in pre-trial settlement discussions.

2. Federal Law Does Not Require Recusal Where a District Court Judge Has Conducted Settlement Discussions Unless Doing So Gives Rise to an Appearance of Bias or Partiality.

Likewise, federal law does not require recusal where a district court judge is involved in pre-trial settlement discussions, even where they involve *ex parte* communications with the parties. *See, e.g.*, *Bosley v. 21 WFMJ TV, Inc.*, 245 F. App'x 445, 453 (6th Cir. 2007) ("[T]o

justify recusal under 28 U.S.C. § 455, the judge's prejudice or bias must be personal or extrajudicial.") (citation omitted); *United States v. Elsass*, No. 2:10-cv-336, 2012 U.S. Dist. LEXIS 29027, at *3–4 (S.D. Ohio 2012) (denying motion to recuse based on court's involvement in mediation); *Novak v. Farneman*, No. 2:10-cv-768, 2011 U.S. Dist. LEXIS 114398, at *7–8 (S.D. Ohio Sept. 30, 2011) (denying motion for recusal based on the court's involvement in settlement negotiations).

Fundamentally, the federal recusal statute, 28 U.S.C. § 455, does not require recusal unless some "extra-judicial" source gives rise to an appearance of bias or partiality. *See Litkey v. United States*, 510 U.S. 540, 554 (1994); *Ball v. Johnson*, 404 F.3d 997, 1005 n.7 (6th Cir. 2005). Settlement discussions are not considered an "extra-judicial source." *Wheeler v. Southland Corp.*, 875 F.2d 1246, 1252 (6th Cir. 1989) (magistrate's statements during settlement conference did not require recusal where none of the comments arose out of extra-judicial sources but only out of proceedings). Put another way, information learned in a judge's judicial capacity in connection with a case, even when facilitating settlement discussions, is not an extrajudicial source and does not require recusal without more.

B. The Trial Judge's Disqualification Requires Recusal from All Post-Trial Proceedings and a New Trial to Avoid the Appearance of Bias or Partiality and Maintain Public Confidence in the Judiciary.

Against this backdrop of state and federal law, the trial judge decided to recuse because he did not think he could be "fair and impartial" after being "so heavily involved in personally trying to mediate a settlement before trial." (Order of Recusal, Apr. 8, 2013 (*Decker* ECF No. 225), at 1.) The trial judge determined that his personal views of the case and the parties were so significantly affected that they removed him from the default presumptions under both state and federal law allowing the trial judge to decide a motion for prejudgment interest. Indeed, absent a

basis for recusal, federal law imposes a duty on a judge to sit where not disqualified. *See, e.g. Laird v. Tatum*, 409 U.S. 824, 837 (1972). GEHC respects the trial judge's decision to recuse and does not fault the trial judge for making this determination. Only the trial judge can determine whether he can continue as a fair and impartial judge. It is not GEHC's place to question the trial judge's determination that he cannot do so here.

1. The Trial Judge May Not Recuse Himself from Only a Portion of the Case.

The Order of Recusal entered on April 8, 2013 states that the trial judge cannot be fair and impartial, and may be called as a witness, in connection with Plaintiffs' motion for prejudgment interest. (*See* Order of Recusal, Apr. 8, 2013 (*Decker* ECF No. 225), at 1.) When the trial judge ordered the clerk to assign Plaintiffs' motion for prejudgment interest to a new judge on April 22, 2013, that order purported to limit the scope of the recusal to Plaintiffs' motion for prejudgment interest. (Order of Recusal and Reassignment, Apr. 22, 2013 (*Decker* ECF No. 269) ("I hereby recuse myself from ruling on Plaintiffs' motion for prejudgment interest.").) At the time of the recusal orders, Plaintiffs' motion for prejudgment interest was the only contested matter pending before the Court. Since then, however, GEHC opposed Plaintiffs' bill of costs. (Opposition, Apr. 24, 2013 (Decker ECF No. 270).) Although the Court's recusal orders may be intended to limit the scope of recusal only to the prejudgment interest motion, GEHC respectfully submits such a limitation is inappropriate. To the extent there is any question on the matter, the law of disqualification makes clear that the trial judge's recusal applies to the balance of this case as a whole.

The plain language of the federal recusal statute requires that a judge's recusal extend to the entirety of a case or "proceeding." That statute provides that "[a]ny justice, judge, or magistrate judge of the United States shall disqualify himself in any *proceeding* in which his

impartiality might reasonably be questioned." 28 U.S.C. § 455(a) (emphasis added). Section 455 specifically speaks of a judge being reassigned or disqualified from a "proceeding." Section 455 defines "proceeding" to include "pretrial, trial, appellate review, or other stages of litigation." 28 U.S.C. § 455(d)(1). This language requires that, when a judge determines that recusal is required, that recusal is from the whole "proceeding"—not a particular motion or issue. The Ninth Circuit clearly articulated this principle in *United States v. Feldman*, 983 F.2d 144 (9th Cir. 1992). There, the trial judge recused himself *sua sponte*, but "only with regard to the administration of the receivership and receivership estate regarding this Court's order of restitution" to avoid the appearance of bias over his financial interest. The Ninth Circuit held that the recusal statutes required complete recusal:

> The judicial recusal statutes, 28 U.S.C. §§ 144 and 455, both speak of a federal judge being reassigned or disqualified from a "proceeding." Section 455 defines "proceeding" to include "pretrial, trial, appellate review, or other stages of litigation." 28 U.S.C. § 455(d)(1). Thus, when a judge determines that recusal is appropriate it is not within his discretion to recuse by subject matter or only as to certain issues and not others. Rather, recusal must be from a whole proceeding, an entire "stage of litigation." We hold that remand to the district court following appellate review is a "stage of litigation," and accordingly, that recusal from only a portion of the proceedings on remand in Feldman's case is not permitted under the recusal statutes.

Id. at 145. The Ninth Circuit concluded that the trial judge erred by limiting his recusal to the restitution portion of the case and not removing himself from all remaining proceedings, even though there was no basis from which to draw an inference of actual bias. *Id.*; *see also Murray v. Scott*, 253 F.3d 1308, 1310–11 (11th Cir. 2001) ("[W]hen a district judge considers recusal, he must consider his potential conflict with regard to the overall case, not just his potential conflict for each separate issue or each stage of the litigation.").

The Sixth Circuit's decision in *In re Aetna Casualty & Surety Co.*, 919 F.2d 1136, 1142–

44 (6th Cir. 1990) (en banc), supports this view as well. There, the trial judge stated his intention to recuse, but continued ruling on various matters unrelated to the recusal. The en banc court, however, took a much wider view of the effect of the recusal and vacated all but those orders involving purely "ministerial duties." *See id*. at 1143–45. In *Aetna*, the Sixth Circuit adopted the Third Circuit's decision in *Moody v. Simmons*, 858 F.2d 137, 142–43 (3d Cir. 1988), which similarly overturned a trial judge's decision that recusal was limited to discrete issues and motions. In *Moody*, the Third Circuit articulated the black-letter principle that when a judge recuses, he may proceed no further in the case:

> Once a judge has disqualified himself, he or she may enter no further orders in the case. His power is limited to performing ministerial duties necessary to transfer the case to another judge (including the entering of "housekeeping" orders).

858 F.2d at 143 (citations omitted). Consideration of GEHC's motion for a new trial and the parties' dispute over the bill of costs, which under Sixth Circuit law involves a parallel inquiry regarding the parties' good faith that prompted the trial judge's recusal in the first place (*see* Opposition, Apr. 24, 2013 (Decker ECF No. 270), at 2, 4), are not "housekeeping" matters. For all these reasons, Section 455 and the law of this Circuit require that the scope of the recusal here extends to the remainder of proceedings.[8]

2. The Trial Judge's Recusal Post-Trial Is Based on Pre-Trial Activities.

The trial judge's post-trial decision that his involvement in pre-trial settlement discussions requires his recusal necessarily means that recusal should have occurred before trial. Not only does the trial judge's Order of Recusal base recusal on his heavy involvement in pre-trial settlement efforts (Order of Recusal, Apr. 8, 2013 (*Decker* ECF No. 225), at 1 ("I was so

[8] Because the Order of Recusal and Reassignment was not entered until three days before the deadline for filing post-trial motions, underscored by the potential uncertainty regarding the identity of the judge who will ultimately decide post-trial motions, GEHC reserves the right to develop its arguments regarding the issues triggered by the recusal further on an appropriate schedule to be determined at the status conference scheduled for May 9.

heavily involved in personally trying to mediate a settlement before trial . . . .")), but the trial judge was also not involved in any settlement efforts involving the parties once the trial began (Supp'l Declaration of M. O'Donnell (Ex. 4), at 5).

Whatever it is about the trial judge's involvement in settlement efforts and the views he formed about the parties that leads him to believe he cannot serve fairly and impartially occurred during pre-trial settlement efforts before trial began on March 5, 2013. In other words, "[t]o the extent that the judge determined that [the bases for questioning his impartiality] mandated recusal after the order [of recusal], they must also mandate recusal before." *Moody*, 858 F.2d at 143. Application of this principle requires vacatur of a trial judge's discretionary rulings that preceded his recusal where the grounds for recusal arose earlier. *See Rohrbach v. AT&T Nassau Metals Corp.*, 902 F. Supp. 2d 523, 530–31 (M.D. Pa. 1995).

By its own terms, the Order of Recusal states that the trial judge cannot proceed because of the effect of his personal efforts to mediate a settlement before trial on his ability to be fair and impartial. Taking this statement at face value, recusal should have occurred as soon as the trial judge formed these views due to his involvement in pre-trial settlement discussions that affected his ability to be fair and impartial—particularly where, as here, that judge has stated "it is possible I could become a witness." (Order of Recusal, Apr. 8, 2013 (*Decker* ECF No. 225), at 1.) It is difficult to see how a judge who provides evidence or testimony can continue to sit in the case. Indeed, that is a mandatory basis for recusal. *See* 28 U.S.C. § 455(b)(1) & (5)(iv); *see also Black v. Kendig*, 227 F. Supp. 2d 153, 156 (D.D.C. 2002) ("I would be acting as witness and judge in the same case. I cannot imagine how any one could possibly defend such a curious mixing of roles. I surely believe that any reasonable person would find that co-mingling highly

offensive to the appearance of impartiality."). Whenever the trial judge's involvement in settlement efforts affected his ability to be fair and impartial, it necessarily occurred pre-trial.

3. The Trial Judge's Recusal Requires a New Trial.

When determining whether to grant a new trial on the basis of the potential for an appearance of bias or partiality, the Court asks whether an "objective observer" would believe that the trial judge's "impartiality might reasonably be questioned." *Liljeberg*, 486 U.S. at 861; *see also Rohrbach*, 902 F. Supp. at 529 ("[T]he vantage point from which disqualification and resulting *vacatur* must be assessed is not that of the lawyer or judge, but that of the objective lay person."). In fact, "recusal is required when a reasonable person would harbor doubts about the judge's impartiality." *In re Aetna Cas. & Sur.*, 919 F.2d at 1143 (quoting *Moody*, 858 F.2d at 142) (citations omitted). Because of the paramount importance in maintaining "the public's confidence in the judicial process," ordering a new trial does not depend on showing that the trial judge actually had any bias or exhibited partiality. *See In re Aetna Cas. & Sur.*, 919 F.2d at 1143, 1145; *see also Liljeberg*, 486 U.S. at 850; *Rohrbach*, 902 F. Supp. at 530–31 (vacating discretionary rulings necessarily tainted by an appearance of partiality or bias).

Here, the trial judge's determination that he could not be fair and impartial in deciding post-trial motions based on his pre-trial involvement in settlement discussions requires a new trial. In *Liljeberg*, the Supreme Court set aside the trial and vacated a final judgment even though the trial judge was unaware of the potential conflict. *Id*. at 868–70. In *Moody*, near the end of protracted and difficult bankruptcy proceedings, the district judge discovered facts giving rise to an appearance of partiality and stated his intention to recuse. Nonetheless, the district court judge disposed of several pending matters before ultimately recusing himself. *Moody*, 858 F.2d at 139. On appeal, the Third Circuit vacated the decisions that followed the district judge's

appreciation of the grounds for recusal because the reasons the judge articulated for recusal "were equally valid before as well as after the entering of the conversion order. To the extent that the judge determined that they mandated recusal after the order, they must also mandate recusal before." *Id*. at 143. As a result of the judge's decision to recuse in *Moody*, the Third Circuit employed vacatur as the remedy. *Id.* at 144. Similarly, in *Rohrbach*, the district judge recused himself partway through the case but maintained that vacating his prior orders would be "absurd." 902 F. Supp. at 527. While the new judge understood his "frustration and being confronted with the specter of wiping out his conscientious handling of this difficult case," he found that vacatur was nonetheless necessary because the "appearance of partiality . . . is sufficient to cast a shadow on the rulings made in this case." *Id*. at 528–30; *see also Rohrbach v. AT&T Nassau Metals Corp*., 915 F. Supp. 712, 718–19 (M.D. Pa. 1996).

In such circumstances, vacatur is required to eliminate "the risk of undermining public confidence in the administration of justice" that follows the recusal of a judicial officer. *Rohrbach*, 915 F. Supp. at 715; *see also In re Aetna Cas. & Sur.*, 919 F.2d at 1143 & 1146 (vacating orders entered after the district judge should have known recusal was necessary to avoid "the risk of undermining the public's confidence in the judicial process"). Just as the judge's determination in *Moody* that recusal was appropriate necessitated vacating earlier orders, the decision of the trial judge to recuse here requires a new trial because he could not be fair and impartial at trial and in deciding post-trial motions due to his involvement in pre-trial settlement negotiations.

As soon as the trial judge's involvement in pre-trial settlement negotiations reached the point where he could no longer be fair and impartial, recusal was required. *See* 28 U.S.C. 455(a) (requiring recusal where judge's "impartiality might reasonably be questioned"). Whether the

trial judge reached that point in July 2012 when Plaintiffs participated in a group mediation before the trial judge, on December 12, 2012 when the trial judge conducted an in-person mediation, or in early 2013 as the parties' settlement discussions continued makes no difference. (*See* O'Donnell Decl. (Ex. 3), at ¶¶ 16–17; Minutes, Dec. 12, 2012 (*Decker* ECF, Non-Document Entry).) Because the trial judge's inability to be "fair and impartial" immediately after the March 2013 trial was based on the settlement discussions that occurred entirely before trial, an objective lay person would conclude that a trial before a judge who harbored such strong feelings that he could no longer be "fair and impartial" was not a fair trial. Therefore, recusal was required before trial and, to maintain public confidence in the administration of justice, the Court should vacate the rulings entered in this case since August 1, 2012 and order a new trial.

III. The Court Should Grant Remittitur or a New Trial Based on the Damages Evidence.

A. The Court Should Grant Remittitur of the Damages Awarded for Economic Loss.

GEHC requests that the court grant remittitur of the jury's award of $5 million. Under Ohio law, damages for economic loss are limited to (a) lost wages, (b) expenditures for medical care, and (c) other expenditures incurred as a result of the injury. *See* Ohio Rev. Code § 2315.18(A)(2). Before trial, Plaintiffs stipulated that their damages did not include any amount for lost wages. (Stipulation (*Decker* ECF No. 169), at 2.) At trial, GEHC moved to admit evidence of Plaintiffs' medical bills relating to NSF, which total less than $20,000. (Trial Tr., Mar. 19, 2013, at 2931:23–2934:24; Notice of Filing, Apr. 10, 2013 (*Decker* ECF No. 259); Supp'l Exhs. in Support of Notice of Filing, Apr. 17, 2013 (*Decker* ECF No. 268).) In response, Plaintiffs agreed they were not seeking damages for past medical expenses and that they sought damages only for future costs identified by their life care planner, Cynthia Wilhelm, Ph.D., who

testified that she relied on Mr. Decker's past medical bills to create the life care plan. (Trial. Tr., Mar. 19, 2013, at 2934:4–15; Trial Tr., Mar. 13, 2013, at 1741:7–9 (testimony of C. Wilhelm, Ph.D.).)

The Court did not find that these proffered medical bills were irrelevant. (Trial Tr., Mar. 19, 2013, at 2933:4 ("I'm not saying they are irrelevant.").) Nor was there any dispute regarding their authenticity. Indeed, under Case Management Order No. 19, which was intended to resolve the admissibility of the documentary evidence for use at trial, the parties agreed and the Court ordered that such records are authentic. (*See* Case Management Order No. 19 (MDL ECF No. 710), at 3–4, ¶ 5.) Accordingly, the prerequisites for admissibility were satisfied. *See, e.g.*, *McQueeney v. Wilmington Trust Co*., 779 F.2d 916, 930 (3d Cir. 1985) (business records were admissible where relevance, authentication, and hearsay objections cannot be seriously disputed); *Adams v. United States*, No. 03-0049-E-BLW, 2009 U.S. Dist. LEXIS 73317, at *13–14 (D. Idaho Aug. 18, 2009) (admitting business record where it would not be "unfair or misleading to introduce this document without a supporting witness" because document is authentic and relevant). But the Court denied GEHC's motion to admit Mr. Decker's past medical bills. (Trial Tr., Mar. 19, 2013, at 2931:23–2934:24.) Whatever the reason for this ruling, it came at the end of trial when GEHC had planned its trial strategy in reliance on the Court's prior rulings.

Notwithstanding the Court's ruling excluding Mr. Decker's medical bills related to his NSF treatment, the Court instructed the jury that it must consider past medical bills in making any award of damages for economic loss:

> In determining the reasonable value of medical, hospital or other related care, treatment, services, products or accommodations you shall consider all of the evidence submitted. Both the original bill

> and the amount accepted as full payment may be considered along with all other evidence to determine the reasonable value.

(Trial Tr., Mar. 20, 2013, at 2984:11–16.) But the Court's exclusion of Mr. Decker's past medical bills prevented the jury from following the Court's instruction to measure the actual costs of managing Mr. Decker's NSF in the past against the life care plan's estimates of future costs. Put another way, the jury was left without the evidence that was necessary to evaluate Dr. Wilhelm's opinions in connection with making an award of damages for economic loss.

The Court may order either remittitur or a new trial. *Gasperini v. Center for Humanities, Inc.*, 518 U.S. 415, 435 (1996) ("The role of the district court is to determine whether the jury's verdict is within the confines set by state law, and to determine, by reference to federal standards developed under Rule 59, whether a new trial or remittitur should be ordered.") (quoting *Browning-Ferris Indus. of Vt., Inc. v. Kelco Disposal Inc.*, 492 U.S. 257, 279 (1989)). The Court should reduce the jury's award if it is beyond the range supportable by proof or the result of a mistake. *See, e.g.*, *Denhof v. City of Grand Rapids*, 494 F.3d 534, 547 (6th Cir. 2007); *Bridgeport Music, Inc. v. Justin Combs Publ'g*, 507 F.3d 470, 484-85 (6th Cir. 2007); *Skalka v. Fernald Envtl. Restoration Mgmt. Corp.*, 178 F.3d 414, 424–25 (6th Cir. 1999); *see also Wightman v. Consolidated Rail Corp.*, 715 N.E.2d 546, 557 (Ohio 1999) (court has inherent authority to remit an award to the amount supported by the evidence); *Jacobs v. Canal Ins. Co.*, 627 F.2d 1090, 1090 (6th Cir. 1980); *Prince v. Jordan*, No. 04CA008423, 2004 Ohio App. LEXIS 6647, at *13 (Dec. 22, 2004) ("[D]amages must be shown with reasonable certainty, and cannot be based upon mere speculation or conjecture, regardless of whether the action is contract or tort.").

Where no evidence supporting an element of damages on which the jury is instructed is presented, a damages award is beyond the range supportable by proof. *Jacobs v. Canal Ins. Co.*,

627 F.2d 1090 (6th Cir. 1990) (granting remittitur where jury's award of damages exceeded the amount of damages proven at trial); *Lee v. Javitch, Block & Rathbone, LLP*, No. 1:06-cv-585, 2008 U.S. Dist. LEXIS 34166, at *15 (S.D. Ohio Apr. 25, 2008) (granting remittitur where damages exceeded proof in claim that a garnishment proceeding exacerbated diabetes). Here, the jury's award of $1 million in damages for economic loss is not supportable where Mr. Decker's total past medical bills related to NSF are less than $20,000. To create the life care plan, Dr. Wilhelm relied on Mr. Decker's past medical bills to create her forward-looking cost projections. (Trial Tr., Mar. 13, 2013, at 1741:7–9 (testimony of C. Wilhelm, Ph.D.).) Without Mr. Decker's past medical bills, however, the jury was unable to evaluate the reasonableness of Dr. Wilhelm's testimony, including the need for any of the items she included in the life care plan or the substantial cost associated with it. Dr. Wilhelm's plan bears no relation to the costs actually incurred for treatment of Mr. Decker's NSF. Without the past medical bills, the jury could not follow the Court's instruction on using the medical bills in considering a damages award, eroding the foundation for the jury's award for economic loss and making it speculative. *See Prince*, 2004 Ohio 7184, at *13 ("[R]esulting damages must be shown with reasonable certainty, and cannot be based upon mere speculation or conjecture.") (citations omitted).

Even a cursory review of the verdict form shows that this error carried over into the jury's calculations of damages for non-economic and consortium damages. The jury awarded damages for non-economic loss in an amount 3.5 times its award of economic loss, and damages for loss of consortium at 50% of the economic loss award. Therefore, a lower damages award for economic loss based on the past medical bills that the Court improperly excluded from evidence would affect the overall damages award. For these reasons, the Court should either

grant remittitur of the damages award to adjust for the actual costs of Mr. Decker's NSF-related medical expenses or a new trial.

B. The Court Should Grant Remittitur of the Damages Awarded for Items Relating to Mental Distress.

Additionally, the Court should grant remittitur to reduce the jury's verdict by the amount included in the life care plan for items relating to mental distress. Specifically, Dr. Wilhelm included amounts in the life care plan for annual treatment by a psychiatrist, regular individual counseling for the remainder of Mr. Decker's life, family counseling, and anti-depressant medication for the remainder of Mr. Decker's life. (P3_0006, at 25, 29 & 35 (attached as Ex. 12).)

In an earlier NSF case set for trial, *Knase v. General Electric Company* (No. 1:08-gd-50026), the Court ruled that Plaintiffs could not claim damages based on mental distress as part of a life care plan absent testimony at trial from the plaintiff that she suffered mental distress as a result of NSF. (*See* Order, Dec. 3, 2010 (*Knase* ECF No. 254), at 2 n.1 ("In the event that Ms. Knase were to testify at trial that she suffers no mental distress as a result of her NSF, Dr. Wilhelm will not be permitted to include this in her life [care] plan.") (attached as Ex. 13).) This ruling resulted from the fact that Dr. Wilhelm is not trained as a psychologist or a psychiatrist and is not a mental health counselor. (Trial Tr., Mar. 13, 2013, at 1799:20–25 (testimony of C. Wilhelm, Ph.D.).) At Plaintiffs' request, the Court ruled that its orders in previous cases, including *Knase*, apply in *Decker*. (Tr. of Telephone Conf., Aug. 13, 2012 (Ex. 9), at 8.) Accordingly, the Court's ruling requiring supporting testimony from the plaintiff to include mental distress damages in a life care plan applies here.

But Mr. Decker testified at trial he does *not* suffer from mental distress as a result of NSF. His testimony on the issue consisted entirely of the following:

> Q. What is the impact your NSF has had on your emotional and your psychological state, Mr. Decker?
>
> A. It is weakened a little bit. I'm still determined to give it a good fight.

(Trial Tr., Mar. 8, 2013, at 1006:17–20 (testimony of P. Decker).) Additionally, Dr. Stephen Freshwater, Mr. Decker's primary care physician, testified that Mr. Decker suffers from no emotional conditions due to NSF alone:

> Q. And can I ask you, are you treating Mr. Decker for emotional issues arising from his NSF condition?
>
> A. I don't know that his treatment for emotional conditions pertains to NSF alone.

(Trial Tr., Mar. 13, 2013, at 1730:18–24 (testimony of Dr. Freshwater).) Dr. Freshwater also testified that he was not aware that Mr. or Mrs. Decker had any problem that required a psychiatrist.

> Q. And, Doctor, have you recommended to either Mr. or Mrs. Decker that they get any kind of psychiatric or psychological counseling?
>
> A. I have not made that recommendation.
>
> Q. Why not?
>
> A. I am not aware that they were having a problem that required the involvement of a psychiatrist.

(*Id.* at 1731:13–19.)

Recognizing that the evidence did not meet the evidentiary standard of his prior order for including mental distress damages in a life care plan (Trial Tr., Mar. 13, 2013, at 1765:7–11), Judge Polster conditioned the admissibility of Dr. Wilhelm's life care plan related to psychological and emotional needs based on the representation that Dr. Derek Fine, Plaintiffs' expert *nephrologist*, would establish their medical necessity (*id.* at 1768:25–1769:5). Without a

proper foundation, the Court made clear it would strike the items relating to mental and emotional distress and the need for psychiatric care from the life care plan. (*Id.*) Plaintiffs failed to lay a proper foundation, but the Court did not strike these items.

As a nephrologist who treats patients with kidney problems, Dr. Fine lacks the qualifications to testify on mental health issues, and his testimony did not support the need for these items in the life care plan. (Trial Tr., Mar. 13, 2013, at 1837:2–20 (testimony of Dr. Fine).) Specifically, Dr. Fine testified that he refers his patients to a psychiatrist for such care and admitted "certainly I don't do the evaluation." (*Id.* at 1837:22–24.) Further, Dr. Fine did not perform a formal psychiatric or mental health evaluation of Mr. Decker. (*Id.* at 1838:9–11.) Yet the Court permitted these items to remain in the life care plan based on Dr. Fine's testimony and because "it is only a thousand or two dollars, quite frankly, it is insignificant." (*Id.* at 1891:12–13.) But the amount of the damages at issue is not determinative of their significance. *See, e.g.*, *David v. ANA TV Network, Inc.*, Nos. 98-2288 & 98-2289, 2000 U.S. App. LEXIS 2477, at *20–21 (6th Cir. Feb. 16, 2000) (granting remittitur where damages were not supported by the evidence); *Lee*, 2008 U.S. Dist. LEXIS 34166, at *19 (remitting economic damages from $603 to $195.26).

Just as the failure to admit evidence of Mr. Decker's NSF-related past medical bills allowed the jury to support its award for economic loss with speculation that compounded and affected the entire damages award, so too did inclusion in the life care plan of items relating to mental distress. Therefore, a lower damages award for economic loss based on the items in the life care plan related to mental distress improperly allowed into evidence notwithstanding the Court's rulings would affect the overall damages award. For these reasons as well, the Court

should either grant remittitur of the damages award to adjust for the actual costs of Mr. Decker's NSF-related medical expenses or a new trial.

CONCLUSION

For the foregoing reasons, GEHC respectfully requests that the Court order a new trial, alter or amend the judgment, or, in the alternative, enter a remittitur reducing the damages awarded.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing was filed electronically on April 25, 2013. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

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